Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

1-34. (Cancelled)

35. (Currently Amended) A method of delivering a lipophilic bioactive material to an interior all of a body vessel from an implantable medical device having an expandable balloon with the lipophilic bioactive material on an outer surface of the balloon, the method comprising the steps of:

inserting the balloon into a body vessel, the balloon having a dried layer containing the bioactive material on the outer surface of the balloon, the balloon being free of a coating atop the bioactive material, the balloon being free of a time-release layer, the balloon being free of a containment material and the balloon being free of a containment layer;

advancing the balloon within the body vessel to a treatment site within the body vessel;

inflating the balloon at the treatment site to contact the bioactive material with an inner wall of the body vessel;

maintaining the bioactive material on the outer surface of the inflated balloon in contact with the inner wall of the body vessel while the balloon is inflated;

deflating the balloon after contacting the bioactive material with the inner wall of the body vessel; and

removing the deflated balloon from the body vessel.

36. (Previously Presented) The method of Claim 35, wherein the balloon is inflated at the treatment site with an inflation time of up to about one minute.

37. (Previously Presented) The method of Claim 35, wherein the bioactive material comprises paclitaxel or a paclitaxel derivative.

38. (Previously Presented) The method of Claim 37, wherein the bioactive material further comprises a diagnostic agent.

39. (Previously Presented) The method of Claim 35, wherein the body vessel is a blood vessel.

40. (Previously Presented) The method of Claim 39, wherein the body vessel is a coronary artery.

41. (Previously Presented) The method of Claim 35, wherein the implantable medical device includes a total of about 5 to about 500 µg of the lipophilic bioactive material on the outer surface of the balloon prior to inserting the medical device into the body vessel.

42. (Previously Presented) The method of Claim 35, wherein the method is performed without implanting a stent within the body vessel.

43. (Previously Presented) The method of Claim 35, wherein the balloon comprises a material selected from the group consisting of: a polyamide, polypropylene, PEBAX and polyethylene.

44. (Previously Presented) The method of Claim 35, wherein the implantable medical device is a balloon

catheter coated with a single layer of the lipophilic bioactive material on the balloon, the single layer consisting essentially of about 5 to about 500 µg of paclitaxel or a paclitaxel derivative deposited on the outer surface of the expandable balloon.

45. (Previously Presented) The method of Claim 35, wherein the lipophilic bioactive material is transferred from the outer surface of the inflated balloon to the inner wall of the body vessel while contacting the outer surface of the inflated balloon with the inner wall of the body vessel.

46. (Previously Presented) The method of Claim 35, wherein the implantable medical device is a balloon catheter having an expandable balloon with about 0.2 to about 20 µg of paclitaxel or a paclitaxel derivative deposited per mm^2 of the outer surface of the expandable balloon and a total of about 5 to about 500 µg of the paclitaxel or the paclitaxel derivative deposited on the outer surface of the expandable balloon; and wherein the method further includes at least one of:

percutaneous insertion of the expandable balloon into a blood vessel;

inflation of the balloon at the treatment site with an inflation time of up to about one minute to contact the paclitaxel or the paclitaxel derivative with the inner wall of the body vessel; or

maintaining the outer surface of the inflated balloon in contact with the inner wall of the body vessel for only the period of the inflation of the balloon.

47. (Previously Presented) The method of Claim 35, wherein the implantable medical device is a balloon catheter having an expandable balloon with a total of about 5 to about 500 µg of paclitaxel or a paclitaxel derivative deposited on the outer surface of the expandable balloon;

the expandable balloon is percutaneously inserted into a blood vessel;

the balloon is inflated at the treatment site with an inflation time of up to about one minute to contact the paclitaxel or paclitaxel derivative with the inner wall of the body vessel; and

the outer surface of the inflated balloon is maintained in contact with the inner wall of the body vessel for only the period of the inflation of the balloon.

48. (Previously Presented) The method of Claim 35, wherein the implantable medical device is a balloon catheter having an expandable balloon with a total of about 0.2 to about 20 μg of paclitaxel or a paclitaxel derivative per mm^2 of the outer surface of the expandable balloon before inserting the balloon into the body vessel.

49. (Currently Amended) A method of delivering a lipophilic anti-angiogenic agent to an interior wall of a blood vessel from a balloon catheter having an expandable balloon with a coating on an outer surface of the balloon, the method comprising:

inserting a portion of the balloon catheter including the balloon with ~~the~~ a dried coating consisting of the lipophilic anti-angiogenic agent into a body vessel, the coating being free of any additional coating atop the anti-angiogenic agent, where the anti-angiogenic agent is not incorporated within a containment layer;

advancing the balloon within the body vessel to a treatment site;

inflating the balloon to directly contact the anti-angiogenic agent in the coating with an inner wall of the body vessel; and

delivering the anti-angiogenic agent to the inner wall of the body vessel while maintaining the anti-angiogenic agent in direct contact with the inner wall of the body vessel while the balloon is inflated.

50. (Previously Presented) The method of Claim 49, where the anti-angiogenic agent is paclitaxel or a derivative thereof.

51. (Previously Presented) The method of Claim 49, where the balloon is attached to a catheter shaft that includes a guide wire lumen and an inflation lumen for inflating the balloon.

52. (Previously Presented) The method of Claim 49, where the anti-angiogenic agent is brought into direct contact with the vessel wall only while the outer surface of the

inflated balloon is maintained in contact with the inner wall of the body vessel.

53. (Previously Presented) The method of Claim 52, where the method is performed without implanting a stent within the body vessel.

54. (Currently Amended) A method of delivering paclitaxel to an interior wall of a blood vessel from a balloon catheter having an expandable balloon with a paclitaxel coating on an outer surface of the balloon, the method comprising:

inserting the balloon catheter without a stent into a body vessel, the balloon catheter having a dried coating consisting of about 5 to about 500 micrograms of a single bioactive coating material consisting of paclitaxel per 25 mm^2 of the gross outer surface area of the balloon, the coating being free of any additional coating and being free of any coating atop the paclitaxel, where the paclitaxel is not incorporated within a containment layer;

advancing the balloon within the body vessel to a treatment site within the body vessel;

inflating the balloon at the treatment site to directly contact the paclitaxel in the coating with an inner wall of the body vessel without implanting a stent within the body vessel; and

delivering the paclitaxel to the inner wall of the body vessel while maintaining the paclitaxel on the outer surface of the inflated balloon in direct contact with the inner wall of the body vessel while the balloon is inflated.